UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel. MICHAEL S. LORD,

Civil Action No.: 3:13-CV-2940

Plaintiffs/Relator,

JUDGE MANNION

- V. -

NAPA MANAGEMENT SERVICES CORPORATION, NORTH AMERICAN PARTNERS IN ANESTHESIA (PENNSYLVANIA), LLC, and POCONO MEDICAL CENTER, **ELECTRONICALLY FILED**

Defendants.

OMNIBUS MEMORANDUM OF LAW IN OPPOSITION TO MOTIONS TO DISMISS

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Relator Michael S. Lord ("Relator") submits this Omnibus Memorandum of Law in Opposition to the Motions to Dismiss filed by Defendants NAPA Management Services Corporation ("NMSC"), North American Partners In Anesthesia (Pennsylvania), LLC ("NAPA-PA", and collectively with NMSC, "NAPA") (Dkt. No. 59), and Defendant Pocono Medical Center ("PMC") (Dkt. No. 66). NAPA and PMC are collectively referred to as "Defendants").

INTRODUCTION

The Relator, a Certified Registered Nurse Anesthetist, filed this *qui tam* action to expose Defendants systemic false billing scheme, to recover the fraudulently obtained federal funds, and for compensation for Defendants' retaliatory conduct and wrongful discharge of the Relator when he raised the false claims concerns to his supervisors at NAPA and PMC. Defendants routinely billed Medicare for "medical direction" services, the highest payment category for anesthesia reimbursement provided by Medicare, despite violating Medicare's basic conditional regulations - known as the TEFRA or Seven Steps rules - which are required prior to reimbursement for such service. As detailed in the Complaint ("Cmpl.") (Doc. No. 1), the Relator routinely witnessed Defendants' anesthesiologists (1) fail to remain physically present and available for immediate diagnosis and treatment of emergencies; (2) fail to perform and accurately document the required pre-anesthetic exam and evaluation; and (3) fail to

participate in the most demanding procedures, including "induction and emergence where applicable." Often, Defendants' anesthesiologists "pre-signed" their medical record attestations (certifying they complied with certain TEFRA Rules) before seeing the Medicare patient or at the beginning of an anesthetic, and without making sure that the TEFRA Rules would be satisfied. If a Medicare provider fails to meet these TEFRA Rules, they must bill Medicare for "medical supervision" services at a lower reimbursement rate. However, Defendants ignored these rules and routinely billed Medicare at the higher reimbursement rate for "medical direction," costing U.S. taxpayers millions of dollars.

When Relator brought these fraud concerns to his supervisors at NAPA and PMC, they retaliated against him, fabricated evidence to paint him as negligent, and ultimately did nothing to cure the issues. Relator was then constructively discharged from his position.

FACTUAL BACKGROUND

The Relator graduated first in his class from nursing school and received his certification as a Certified Registered Nurse Anesthetist ("CRNA") in May 2011. Cmpl. ¶¶46, 53. The Relator began work for NAPA-PA at PMC in June 2011 under the supervision of Dr. Anthony Nostro (Chief of Anesthesiology at PMC). ¶54. ¹ During his employment, the Relator was consistently recognized for

¹ "¶" refers to paragraphs in the Complaint.

excellent job performance. ¶55. The Relator also applied for and was accepted to Yale University where he completed a Doctor of Nursing Practice degree. ¶59.

Throughout his employment with NAPA-PA at PMC, Relator witnessed NAPA's systematic effort to overbill Medicare by claiming it delivered "medically directed" services, when NAPA only provided "medical supervision" services to Medicare patients. ¶69.

The Centers for Medicare and Medicaid Services ("CMS") administers the Medicare and Medicaid programs. 42 U.S.C. §§ 1302, 1395hh. When paying for anesthesia services, CMS regulations distinguish the amount of reimbursement among four levels of services for anesthesia reimbursement: (i) Personally Performed; (ii) Medical Direction; (iii) Medical Supervision; and (iv) Not Medically Directed. 42 C.F.R. §§ 414.46, 414.60. At issue are claims for payment at the Medical Direction level of reimbursement. Medical Direction level reimbursement applies only when an anesthesiologist directs a qualified individual, such as a CRNA, in no more than four (4) concurrent anesthesia cases. 42 C.F.R. § 414.46(d)(ii). To obtain reimbursement for Medical Direction, Medicare regulations require the anesthesiologist to complete seven steps:

- (1) For each patient, the physician—
 - (i) Performs a pre-anesthetic examination and evaluation;
 - (ii) Prescribes the anesthesia plan;

- (iii) Personally participates in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence;
- (iv) Ensures that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified individual as defined in operating instructions;
- (v) Monitors the course of anesthesia administration at frequent intervals;
- (vi) Remains physically present and available for immediate diagnosis and treatment of emergencies; and
- (vii) Provides indicated post-anesthesia care.

42 C.F.R. § 415.110(a)(1) (the "TEFRA Rules"). ¶37. An anesthesiologist must document "in the patient's medical record" that each step was completed, "specifically documenting that he or she performed the pre-anesthetic exam and evaluation, provided the indicated post-anesthesia care, and was present during the most demanding procedures, including induction and emergence where applicable." 42 C.F.R. § 415.110(b).

Daily, the Relator witnessed Defendants' anesthesiologists fail to remain "physically present and available for immediate diagnosis and treatment of emergencies." *See, e.g.*, ¶45, 82. Defendants routinely provided morning and afternoon lunch breaks to CRNAs and made it impossible for the anesthesiologists to leave the patient's side without having another physician to cover concurrent cases. NAPA's Break Model caused the anesthesiologists not to be "physically present" for the other concurrent medically directed cases every time a CRNA was

provided with a break and where the physician failed to obtain coverage. ¶¶71-72, 225-227.

The Relator raised his concerns about this systematic problem and false billing to his supervisors, including Dr. Nostro, and to the chief compliance officers at NAPA and PMC. ¶161-162, 167-173, 185, 187. However, the Defendants did nothing to rectify the ongoing fraudulent conduct. ¶¶174, 189. Instead, they retaliated against him. ¶191. Defendants' anesthesiologists were told to "watch out" for the Relator because he "is the police." ¶192. The Relator was also stripped of shifts in the cardiovascular operating room ("CVOR"), even though he was the only CRNA at PMC to hold a cardiac surgery sub-specialty certification. ¶193. Although the Relator reported this retaliation to NAPA's compliance officers, nothing was done. ¶195. It got worse. The Defendants sabotaged his efforts to obtain new employment by providing negative recommendations to prospective employers at Penn State Hershey Medical Center and Geisinger Health System. ¶196. The Defendants also instructed employees not to provide reference letters for the Relator. ¶197. NAPA also refused to provide an employment evaluation for the Relator, which meant he would be precluded from renewing his credentials to work at PMC. ¶¶4, 168, 187, 199, 252. And PMC failed to procure the documentation and evaluation from their medical staff for the Relator's re-credentialing in 2013. ¶¶187-88, 199. Relator was also

assigned to the most "call shifts" - additional shifts in which the Relator had to stay late and be on call and within 30 minutes of PMC. ¶201.

In the final event that caused Relator's constructive discharge, on June 14, 2012, Dr. Wu Chen, a NAPA anesthesiologist, falsely claimed to Dr. Nostro that the Relator refused to follow her instructions and was insubordinate regarding the administration of a beta-blocker to a patient. ¶202. To falsely paint the Relator as negligent, Dr. Chen falsified a copy of the patient's medical record in an effort to have Relator fired. ¶202-203. Relator, however, obtained the original patient record on June 20, 2012 revealing that Dr. Chen's claims were false and that she falsified a copy of a patient's record. ¶206. Even when Dr. Chen's conduct was revealed by the Relator, Defendants refused to investigate or discipline Dr. Chen. ¶209. Instead, NAPA's compliance officer, Leslie Russo, tried to sweep the event and Relator's fraud allegations under the rug by attempting to persuade the Relator to resign and sign a non-disclosure agreement. ¶¶210-11. Russo also told the Relator there was "no reason to involve an attorney." ¶211.

The day after Relator discovered Dr. Chen's falsified patient record, Relator was scheduled for a day off. ¶213. NAPA took this opportunity to lock the Relator out of NAPA's e-mail and computer systems, and then informed him he would no longer receive a salary. *Id.* On June, 26, 2012, the Relator requested a dispute resolution meeting with NAPA under his employment contract. ¶216.

However, NAPA failed to timely respond as required by Realtor's employment agreement and by July 5, 2013, Relator understood their failure to respond as a constructive discharge of his employment. *Id*.

LEGAL STANDARD

In order "to survive a motion to dismiss [under 12(b)(6)], the complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)) (quotations omitted). "A complaint satisfies the plausibility standard when the factual pleadings allow the court to draw the reasonable inference that the defendant is liable for misconduct alleged." *Burtch v. Millberg Factors, Inc.*, 662 F. 3d 212, 210-11 (3d Cir. 2011) (citing *Iqbal*, 556 U.S. at 678) (brackets and quotations omitted).

The court's inquiry in determining the sufficiency of a claim when considering a Rule 12(b)(6) motion is "broken up into three parts: (1) identifying the elements of the claim, (2) reviewing the complaint to strike conclusory allegations, and then (3) looking at the well-pleaded components of the complaint and evaluating whether all of the elements identified in part one of the inquiry are sufficiently alleged." *Malleus v. George*, 641 F. 3d 560, 563 (3d Cir. 2011) (citing *Iqbal*, 556 U.S. at 675, 679).

Defendants also invoke FED. R. CIV. P. 9(b). To satisfy the "particularity"

requirement of 9(b) at the pleadings stage, a relator may identify "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 155–56 (3d Cir.2014) (internal citations omitted). Notably, this standard embraced by the Third Circuit – following the First, Fifth, and Ninth Circuits – is more lenient than the standard used by the Fourth, Sixth, Eighth, and Eleventh Circuits. *Id.* at 155-57. Under the Third Circuit's more "nuanced" approach, a relator need not show "representative samples' of the alleged fraudulent conduct, specifying the time, place, and content of the acts and the identity of the actors" because "requiring this sort of detail at the pleading stage would be 'one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates." Foglia, 754 F.3d at 155-56 (quoting U.S. ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir.2009)). Finally, "Rule 9(b) does not require plaintiffs to allege every fact pertaining to every instance of fraud when a scheme spans several years." *United States ex rel.* Shemesh v. CA, Inc., 89 F. Supp. 3d 36, 52 (D.D.C. 2015) (quoting United States ex rel. Williams v. Martin-Baker Aircraft Co., Ltd., 389 F.3d 1251, 1259 (D.C.Cir.2004)).

ARGUMENT

I. THE COMPLAINT SUFFICIENTLY PLED FALSE CLAIMS ACT VIOLATIONS AGAINST NAPA

Relator's FCA claims are actionable because NAPA billed Medicare the higher reimbursement rate for "medical direction," even though they regularly failed to satisfy Medicare's TEFRA Rules and should have billed their services as "medical supervision." To establish a *prima facie* FCA violation under section 3729(a)(1), a relator must prove that "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment;² (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." U.S. ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 304–05 (3d Cir. 2011). Further, the false claims must be material. *Universal Health Servs.*, *Inc.* v. United States ex rel. Escobar, 136 S. Ct. 1989, 1996 (2016) ("Escobar I"). A claim is factually false, as in this case, when a claimant misrepresents the goods or services it provided to the government. Wilkins, 659 F.3d at 304. In addition, a claim can also be legally false if a claimant seeks reimbursement without disclosing that it violated regulations that affected its eligibility for payment. *Id*.

Relator sufficiently alleges NAPA knowingly presented factually false claims because they sought reimbursement for "medical direction," when all that

² NAPA does not contest that they presented claims to the United States Government for payment.

was provided to Medicare's plan members was "medical supervision," as NAPA routinely violated Medicare's TEFRA Rules; and NAPA knew that its practice model violated Medicare's rules.

A. NAPA Anesthesiologists Were Not "Immediately Available"

Relator alleges that NAPA anesthesiologists routinely provided CRNAs multiple breaks, while medically directing other concurrent cases. Cmpl. ¶69-90. When personally treating patients while a CRNA is on break, the anesthesiologist cannot leave the patient's side and therefore is not "immediately available" to the other patients in his/her other concurrent cases. *Id.* Therefore, billing Medicare for the higher cost of medical direction for each of those cases is fraudulent because the anesthesiologist was not immediately available as required by TEFRA Rules. Moreover, Medicare's reimbursement scheme permits claimants to simply seek another more appropriate category when the TEFRA Rules are not satisfied, *e.g.*, medical supervision. However, NAPA only submitted claims for "medical direction" whether or not it was in compliance with TEFRA Rules.

In opposition to Relator's well-pled FCA claim, NAPA argues that Relator's allegations are factually incorrect because NAPA is a "group practice" and "multiple physicians and CRNAs are on site at any given time and are available to help satisfy the TEFRA Rules when a physician provides break coverage for a

CRNA." NAPA Br. at 8-9.³ However, on a motion to dismiss, NAPA's factual challenge of Relator's allegations is inappropriate. Relator alleged NAPA's anesthesiologists were not immediately available (Cmpl. ¶69-73), and provided examples of more than a dozen, specific instances of where NAPA failed to comply with the TEFRA Rules, but billed Medicare for "medical direction" anyway. *See*, *e.g.*, Cmpl. ¶75-90. Relator is entitled to all favorable inferences, and NAPA's speculative factual contentions are inappropriate at this stage of the litigation.

Even if the Court were to give any credence to NAPA's factual contentions, NAPA's argument still fails because it is a disputed issue of fact. Relator's detailed allegations directly contradict NAPA's assertion (NAPA Br. at 9) that the Relator could not have known which other NAPA anesthesiologists were available to assist with medical direction. For instance, in Paragraph 84, Relator alleges that on October 15, 2012, Dr. Marcus was medically directing Relator involving a Medicare patient. Cmpl. ¶84. When "Relator called Dr. Marcus requesting assistance with extubation," however, "Dr. Marcus informed relator he was giving CRNA Elissa Shannon a lunch break in another operating room." *Id.* "Dr. Marcus was not immediately available throughout the course of [the anesthetic of Relator's

³ "NAPA Br." refers to NAPA's Memorandum of Law in Support of its Motion to Dismiss. Doc. No. 59.

patient] and did not arrange adequate medical direction coverage in his absence as required by Medicare." *Id.* Had another anesthesiologist been assigned to be immediately available, Relator would have found medical direction from that anesthesiologist, and the medical record, as required by CMS, would have reflected this. Relator knew there was no other anesthesiologist fulfilling the "immediately available" requirement (as defined by CMS), because Relator himself could not get assistance. *See also, e.g.,* ¶72, 76, 77, 78, 79, 80, 81, 86, 87. NAPA's implied assertion that casual availability is equal to TEFRA's immediate availability requirements is nothing more than self-serving speculation, and plainly at odds with CMS' directives.

The Relator's allegations defeat NAPA's speculation that there must have been other anesthesiologists around because NAPA is a group practice. *Compare with* NAPA Br. at 10 ("even assuming that a physician who provides break relief while medically directing other cases must prospectively arrange for coverage of his or her concurrent cases during that period, Lord does not explain if or how he knows that the doctors in his examples failed to do so").

PMC is a large hospital complex. Even if there are anesthesiologists somewhere in the hospital available to respond to an emergency, NAPA could never satisfy the TEFRA Rules because without specifically assigning a medical directing anesthesiologist to be <u>immediately available</u> at all times. The fact that

there may be some anesthesiologist somewhere in the building does not come close to satisfying the TEFRA rules. Further, the Centers for Medicare & Medicaid Services ("CMS") manual makes it clear that each "medical record must indicate that the services were furnished by physicians and identify the physicians who furnished them." Cmpl. ¶44. Thus, NAPA's argument taken to its logical conclusion would require them to provide the names of every NAPA anesthesiologist at PMC on each medical record during the time the anesthesia services were provided. While also showing that doing so would not exceed these other anesthesiologist's respective maximum concurrent medically directed caseload.

Next, NAPA argues that Relator acknowledged the TEFRA Rules may be satisfied if NAPA had taken certain steps to ensure their compliance. NAPA Br. at 8, citing Cmpl. ¶225 (referencing CMS Payment for Anesthesiologist Services, RUV. 1859, Issue November 20, 2009.) The key, however, is that NAPA did not take any of those steps to ensure that TEFRA was complied with, including: (a) a second anesthesiologist assuming temporary medical direction responsibility for the anesthesiologist providing temporary relief; (b) the relieved CRNA remaining in the immediate area so he can return immediately to the procedure; or (c) a specified anesthesiologist remaining available to provide substitute medical direction services for the anesthesiologist providing temporary relief. NAPA took

none of these steps to ensure that the TEFRA Rules were satisfied. Instead, they just failed to comply with TEFRA, but still billed Medicare for "medical direction" no matter what the circumstances of the services provided were.

NAPA's reliance on U.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC, 833 F. 3d 874, 878 (8th Cir. 2016) is misplaced. Citing Donegan, NAPA argues that Relator's allegations about the anesthesiologists' unavailability during emergence fail because "emergence" is a broadly defined term "that may include a patient's recovery in the post-anesthesia care unit (PACU)." NAPA Br. at 12. This strawman argument conflates two distinct requirements. The TEFRA Rules require both that the anesthesiologist "[r]emain physically present and available for immediate diagnosis and treatment of emergencies" and "[p]ersonally participate[] in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence." 42 C.F.R. § 415.110(a)(1)(iii) & (vi). Therefore, even if the term "emergence" is defined broadly enough to capture the anesthesiologist's eventual return to the patient during recovery perhaps in the PACU, NAPA still may not bill Medicare for medical direction when the anesthesiologist was not immediately available during the patient's administered anesthesia, or failed to meet any other TEFRA Rules, such as failing to participate in the most demanding aspects of the anesthesia plan – including extubation when a patient's airway is at greatest risk.

B. NAPA's Pre-Signed Attestations Violate TEFRA Rules

Relator alleges that NAPA's Medicare billing practices are improper because its anesthesiologists failed to accurately "document[] that he or she performed the pre-anesthetic exam and evaluation, provided the indicated postanesthesia care, and was present during the most demanding procedures, including induction and emergence where applicable," as required under 42 C.F.R. § 415.110(b). Cmpl. ¶¶91-122. NAPA recklessly "pre-signs" their attestations without making sure the TEFRA Rules have been met. *Id.* This is yet another reason NAPA should not bill for "medical direction." See U.S. ex rel. Estate of Donegan v. Anesthesia Assocs. of Kansas City, PC, No. 4:12-CV-0876-DGK, 2015 WL 3616640, at *3 (W.D. Mo. June 9, 2015), aff'd sub nom. United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC, 833 F.3d 874 (quoting CMC, which disagreed with the more lenient standard for medical documentation proposed by the American Society of Anesthesiologists).

Each pre-signed attestation was patently false. Relator alleged that "NAPA anesthesiologists at PMC routinely pre-signed attestations stating: 'I was present for induction, key portions of the procedure and emergence: and immediately available throughout.'" Cmpl. at ¶91. Because those anesthesiologists had not

done so at the time of the signature, those pre-attestations were false.⁴

Furthermore, when the attestations were pre-signed, the anesthesiologists knew full well that they would be providing breaks to CRNAs throughout the day which

would violate TEFRA. NAPA cannot establish that the pre-signed attestations

were truthful upon subsequent alteration by anesthesiologists.

NAPA argues that Relator failed to allege "(a) that the patient was a Medicare patient, (b) that NAPA submitted claims for Medicare reimbursement, or (c) that any claims were for medically directed services." NAPA Br. at 13. This is a disingenuous argument since the statement the anesthesiologist certifies ("I was present for induction, key portions of the procedure and emergence: and immediately available throughout."), as alleged in Paragraph 91, is meant specifically for Medicare reimbursement for medical direction services. These allegations are more than enough to satisfy the "particularity" requirement of Rule 9(b) at the pleadings stage, as Relator successfully identifies "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia*, 754 F.3d at 155–56.

NAPA next argues that the Complaint fails to identify the names of every

⁴ NAPA argues that eventually the anesthesiologists may have completed the presigned attestation with correct information, ultimately making those attestations true. NAPA Br. at 14. That argument fails, however, because those attestations were false when signed, nor can NAPA subsequently correct these attestations after having failed to medically direct their concurrent cases.

patient that had a pre-signed attestation and whether they received Medicare benefits. NAPA Br. 13. First, the Relator is not required under the law to allege every instance of fraudulent conduct at NAPA to adequately state a claim. *Shemesh v. CA, Inc.*, 89 F. Supp. 3d at 52. Second, the Relator did identify the names and Medicare statuses for those pre-signed attestations that Relator could identify. Cmpl. ¶¶ 102, 118. Lastly, the Complaint identifies every patient NAPA understood was a Medicare patient. *See, e.g.*, Cmpl. ¶¶ 74, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 89, 90, 102, 118. Moreover, each NAPA anesthesia record contains a sticker identifying the Medicare patients. The copies of the anesthesia records attached to Relator's Disclosure Statement have those stickers.

Finally, Relator alleges that NAPA anesthesiologists routinely <u>falsified</u> physical examinations. Cmpl. at ¶145 ("The falsification of a patient's preanesthetic physical examination violated the Medicare and TEFRA Rules for medical direction in those cases which involved Medicare patients.").⁵

⁵ Curiously, NAPA argues that Relator's allegations regarding pre-signed attestations fail because they "do not allege the submission of any Medicare claims." NAPA Br. at 14. NAPA is wrong. *See* Cmpl. ¶93 ("on information and belief, these false forms were forwarded to the NAPA Defendant's billing department indicating that all Medicare requirements were fulfilled."); ¶97 ("[Relator] routinely witnessed anesthesiologists pre-sign the Anesthesia Records in violation of Medicare and TEFRA rules and in furtherance of their scheme to fraudulently bill for medically directed services").

C. NAPA Knew Its Practice Model Was Not Compliant With TEFRA Rules

The Complaint provides numerous allegations that make it clear that NAPA knew its practice model was not compliant with TEFRA Rules. For example, on March 6, 2012, Relator witnessed Dr. Nostro, NAPA's Chief of Anesthesiology at PMC, refuse to sign a patient's anesthesia record because he knew his concurrent case ratio would have been too high. Cmpl. ¶163. Instead, Dr. Nostro asked Relator to find someone who could sign the record (and therefore falsely state that they were present for induction). *Id*.

In addition, Leslie Russo, NAPA's compliance officer, informed Relator by letter that practice of pre-signing attestations was not proper and would "ensure that Dr. Nostro conducts an educational in-service with both attendings and CRNAs to ensure that this does not occur." Cmpl. ¶96. Thus, NAPA's own compliance officer was aware that pre-signing attestations was wrong, yet the practice continued unabated throughout 2013. *Id*.

D. Materiality

The FCA violations that Relator alleges are material. Relator specifically alleged that there are different levels of Medicare reimbursement, and NAPA improperly charged Medicare for medical direction when it should have sought payment for medical supervision only. Cmpl. ¶¶3, 60-61, 73, 170. The materiality of NAPA's FCA violations was conceded by NAPA's Vice President, HR &

Compliance, Leslie Russo, who reiterated NAPA's purported commitment to the TEFRA Rules required for medical direction in her March 12, 2013 letter to Relator: "in order to make sure that the message is being received by the anesthesiologists, we are sending out a copy of the anesthesia requirements for medical direction, and alerting the anesthesiologists that they must perform the pre-anesthesia evaluation in accordance with those requirements." Cmpl., ¶186 (Disclosure Statement, Ex. 19)

Attempting to rebut Relator's allegations, NAPA improperly introduces and relies on purported facts that are not contained in the Complaint, including a 2013 guidance issued by one Medicare Administrative Contractor ("MAC") attached to the declaration of an attorney, David M. Vaughn, which suggests that certain "not medically directed" category (billed under modifier QZ) would still be paid the same amount as "medical direction." NAPA Br. at 19-20. On a motion to dismiss, NAPA's introduction of facts from outside the Relator's complaint is inappropriate, and should be rejected. Tri3 Enterprises, LLC v. Aetna, Inc., 535 F. App'x 192, 195 (3d Cir. 2013) ("[u]nless the court converts a motion to dismiss into a motion for summary judgment, it is generally confined to the four corners of the complaint when evaluating its sufficiency"). Factual controversies between Relator's allegations and NAPA's assertions cannot be resolved at this stage of the litigation and should be resolved by a jury after discovery has taken place.

Ancherani v. City of Scranton, No. 3:13-CV-02595, 2014 WL 3900232, at *7–8 (M.D. Pa. Aug. 8, 2014) (the court looks only to the "four corners of the Complaint" and cannot consider information contained outside the complaint on a motion to dismiss).

Moreover, the MAC guidance referenced in the Vaughn declaration is no longer available on CMS' website. The guidance currently available on CMS' website directly contradicts Mr. Vaughn's contention. According to the CMS Manual System:

if the physician leaves the immediate area of the operating suite for other than short durations or devotes extensive time to an emergency case or is otherwise not available to respond to the immediate needs of the surgical patients, the physician's services to the surgical patients are supervisory in nature. Carriers may not make payment under the fee schedule.

See, e.g., Cmpl. ¶44 (emphasis added).⁶ This guidance makes clear that if an anesthesiologist in not immediately available, whether because he left the room or is personally performing another anesthesia case while a CRNA is on a break, then "the physician's services to the surgical patients are supervisory in nature" and cannot by billed as "medical direction."

Similarly, NAPA claims that they could have billed their services under the

⁶ See 42 C.F.R. 414.46 (emphasis added) (available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf.)

"QZ modifier" reimbursement level relating to CRNA Only services, for which Medicare's reimbursement is the same or similar to medical direction. NAPA Br. 20. This, too, is a red herring because they did not bill for the QZ modifier and cannot, *ex post facto*, do so. Further, CMS specifically requires providers to bill as medical supervision in any case where there is a failed medical direction. *See* 42 C.F.R. 414.46 (if an anesthesiologist is not immediately available, "the physician's services to the surgical patients are supervisory in nature.")

Finally, NAPA's reliance on *Escobar I* is unavailing because that case addresses materiality in connection with legally false claims under the "implied false certification" theory of FCA liability, whereas Relator here alleges factually false claims. The issue is not whether NAPA's misrepresentations about compliance with the regulatory requirement were material to the government's payment decision; rather, the issue is that NAPA sought – and received – Medicare reimbursement for a more expensive service (medical direction) after performing less costly services (medical supervision). Even if Relator's claims are construed as "implied false certification" claims, the *Escobar* supports Relator's claims because violating the TEFRA Rules goes to the "very essence" of Medicare reimbursement for NAPA's anesthesia services. *United States ex rel. Escobar v.* Universal Health Servs., Inc., 842 F.3d 103, 110 (1st Cir. 2016) ("Materiality is more likely to be found where the information at issue goes 'to the very essence of

the bargain"), citing Escobar I, 136 S. Ct. at 2003.

E. Relator's FCA Claims Are Not Limited to the Duration of His Employment with Defendants

Relator's FCA claims capture the entire fraudulent scheme that he brought to light, and are not temporally limited to the duration of his employment with Defendants. U.S. ex rel. Galmines v. Novartis Pharm. Corp., 88 F. Supp. 3d 447, 456 (E.D. Pa. 2015) (the Court should "allow original-source relators to pursue the entire fraudulent scheme for which they have direct and independent knowledge of the operative substantive facts, and not [] limit relators to the specific time periods for which they have direct and independent knowledge"); see also, Dalitz v. AmSurg Corp., No. 2:12-CV-2218-TLN-CKD, 2015 WL 8717398, at *3 (E.D. Cal. Dec. 15, 2015) ("The mere fact that relator plaintiffs here allege that they worked for defendants [] for a limited period of time does not mean that their FCA claims are necessarily limited in scope to only that time."). This is especially true because Relator alleges that Defendants' illegal practices were continuing despite Relator's persistent efforts to report same to the management. Cmpl. at ¶190; Galmines, 88 F. Supp. 3d at 4557 (FCA policy reasons for allowing a relator recover for the entire fraudulent scheme, rather than only the period of employment). NAPA's argument that Counts I and II should be dismissed for claims before June 2011 or after June 2013 should be rejected. NAPA Br. at 6-7.

II. THE COMPLAINT SUFFICIENTLY PLED A WHISTLEBLOWER RETALIATION CLAIM AGAINST PMC⁷

A. PMC Is Liable For Whistleblower Retaliation Under the FCA⁸

Relator was employed by NAPA, and NAPA was an independent contractor for PMC. Cmpl. ¶¶ 6, 54. Thus, the Relator was an agent of an independent contractor to PMC and, as such, may state claim for FCA retaliation against PMC.

PMC claims that since Relator was not employed by PMC and has not alleged any agency relationship, it cannot be held liable for any violations of the FCA. PMC Br. 2, 18-19. This is incorrect. In 2009, Congress amended § 3730(h) to remove any reference to retaliation "by his or her employer," and expanded the protection from only employees to "employees, contractors, and agents."

**Lampenfeld v. Pyramid Healthcare, Inc., No. 3:14-CV-0283, 2015 WL 926154, at **4 (M.D. Pa. Mar. 4, 2015). In addition, in 2009 the FCA was amended to expand its coverage from just "employee[s]" to "[a]ny employee, contractor, or agent..."

**See 31 U.S.C. § 3730(h) (emphasis added). Even though PMC is not Relator's "employer," PMC is still liable for its retaliation against the Relator.

⁷ Since certain of Relator's state law claims are duplicative of his Federal whistleblower retaliation claims, Relator hereby withdraws Counts IV, V, and VI. This does not affect Relator's state law breach of contract claim asserted against NAPA.

⁸ Since NAPA has not moved to dismiss the Relator's FCA whistleblower retaliation claims or the breach of contract claim, Relator only addresses these claims as they relate to PMC.

In *Halasa v. ITT Educ. Servs., Inc.*, 690 F.3d 844, 847–48 (7th Cir. 2012), the court denied a motion to dismiss retaliation claims of an independent contractor. The court explained that besides preventing employers from terminating employment for conduct that is "in furtherance of an action under [the FCA," in 2009, Congress amended the statute to protect employees from being fired for undertaking "other efforts to stop" violations of the Act, such as reporting suspected misconduct to internal supervisors. *Id.* at 848. In *Tibor v. Michigan Orthopaedic Inst.*, 72 F. Supp. 3d 750, 757–60 (E.D. Mich. 2014), defendant hospital unsuccessfully moved to dismiss relator's FCA retaliation claim arguing that the hospital was not the employer, where the hospital provided clinical privileges to the plaintiff (a surgeon), but her employment was with Michigan Orthopaedic Institute. *Id.* at 757.

Here, Relator was employed by NAPA, an independent contractor of PMC, and is protected from retaliatory conduct by PMC. Relator had to comply with all of PMC's rules and regulations (as was required of all PMC medical staff whether employed by PMC or not) and was granted privileges to work at the hospital by PMC. Moreover, the Complaint alleges that after the Relator informed PMC's compliance department about the Medicare fraud that was occurring at PMC, nothing was done to stop the fraud and PMC failed to procure the required documentation and supervisory evaluation necessary for Relator to further retain

clinical privileges to work at PMC. Cmpl. ¶¶4, 168, 187, 199, 252. Thus, PMC, in concert with NAPA, retaliated against the Relator.

III. CONCLUSION

For the foregoing reasons, Relator respectfully requests that the Court deny Defendants' Motions to Dismiss in their entirety and for such other relief as the Court deems just and proper.

Dated: May 3, 2017

Respectfully submitted,

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UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel. MICHAEL S. LORD,

Plaintiffs/Relator,

- V. -

NORTH AMERICAN PARTNERS IN ANESTHESIA, LLP, NAPA MANAGEMENT SERVICES CORPORATION, NORTH AMERICAN PARTNERS IN ANESTHESIA (PENNSYLVANIA), LLC, and POCONO MEDICAL CENTER,

Defendants.

Civil Action No.: 3:13-CV-2940

JUDGE MANNION

ELECTRONICALLY FILED

CERTIFICATE OF SERVICE

SCOTT V. PAPP, ESQUIRE, hereby certifies that on the 3rd day of May, 2017, he caused to be served true and correct copies of the foregoing OMNIBUS MEMORANDUM OF LAW IN OPPOSITION TO MOTIONS TO DISMISS, by ECF on all counsel of record.

LOWEY DANNENBERG COHEN & HART, P.C.

/s/ Scott v. Papp, Esquire SCOTT V. PAPP, ESQUIRE